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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/344,226	06/25/1999	RONALD H. CHIARELLO	2574.008US0	8804

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PETER G. CARROLL
MEDLEN & CARROLL, LLP
220 MONTGOMERY STREET, STE.2200
SAN FRANCISCO, CA 94104

EXAMINER

SOLOLA, TAOFIQ A

ARTUNIT PAPER NUMBER

1626

DATE MAILED: 02/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/344,226

Applicant(s)
Chiarello et al.

Examiner
Taofiq A. Solola

Art Unit
1626



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 7, 2002

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1 and 3-20 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1 and 3-20 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

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Claims 1, 3-20 are pending in this application.

Claim 2 is canceled.

Request for Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.117(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/07/02 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-9, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phraseology "under covalent bonding conditions," claim 1, line 26, is not defined in the claim so as to ascertain the metes and bounds of the invention. Therefore, claims 1, 3-9, are indefinite. Claim 1 must recite specific steps as to how one of ordinary skill in the art would perform the covalent bonding. The claims must recite the reagents, the reaction times and

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conditions involve in the process. A claim must stand alone to define the inventions, and incorporation into the claims by express reference to the specification or an external source is not permitted. Ex parte Fressola, 27 USPQ 2d 1608, BdPatApp & Inter. (1993).

The terms “organic compound” line 25, claim 1, and “biomolecule” claim 3, line 2, and claim 5, line 1, renders the claims indefinite. It is not possible to determine the structures of the compounds included and/or excluded by the term, and subsequently the covalent products. Under US patent practice, the product of a process claim determines the class and subclass of the process. Such class and subclasses must be searched. Therefore, it is not possible to classify, and perform a complete search of the claims. These also apply to the phraseology “Ra and Ra’ are non-hydrogen substituents,” in claim 1, line 23, and therefore claims 1, 3-9, are indefinite. The substituents amount to everything in a textbook and/or a catalogue of organic chemistry, except hydrogen. Under US patent practice a claim must recite what is being claimed.

Claim 10, recites “a conjugated substance and a fluorophore, . . . the fluorescent conjugate having the structure [of] formula 1. This is confusing and therefore claims 10-20 are indefinite. By replacing “fluorescent” with “fluorophore” the rejection would be overcome.

Applicants’ arguments filed 1/07/02 have been fully considered but they are not persuasive. Applicants argue that a functional claim is appropriate. To support the contention applicants refer the Examiner to MPEP § 2173.05(g). This is not persuasive because the claim is directed to a process of making, and “conjugating the fluorophore . . . under covalent bond

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forming conditions" is the novel and critical step of the process. Under US patent practice such critical step cannot be in functional language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al., US 4,647,675, in view of Earnest et al., US 4,900,686, and King US 5,846,737.

Applicants claim conjugated rhodamine dyes of generic formula 1, having several substituents. For example, R1 to R14 are each H; R2-R9 are each alkyl; Ra is alkyl, cycloalkyl or aryl and Z is a linker and the conjugated substance. Also, R1-R2, R5-R6, and R9 to R14 are each halogen. Mayer et al., teach rhodamine dyes having formula 1, with several substituents. For example, R, R1 to R3 are each H; R4 and R5 are each alkyl, cycloalkyl; one of R4 and R5 is H or aryl; X and Y are each H or chlorine. See the abstract, specific species in columns 1-7, and claims 1-5. The difference between the instant invention and that of Mayer et al., is that in the instant invention the compounds are being claimed as conjugate while Mayer et al., do not teach the conjugates. However, Earnest et al., teach rhodamine dyes ~~having generic formula 1.~~ ~~Earnest et al., also teach that, the dyes~~ are commonly used as conjugates in biological diagnostic

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assays, and that the most commonly use dyes are fluorescent dyes (column 1, lines 1-40). King teaches rhodamine dyes ^{and} ~~having~~ formulae shown in columns 1-4, and their method of use as conjugate of peptides, proteins nucleotides, etc. (column 1, lines 1-4). King also, teaches the conjugation of rhodamine dyes to bacteria, virus, yeast, and to immobilized solid or semi-solid support, such as polymer, membrane, polymeric particle, (microsphere), etc. See column 10, lines 10-18. Therefore, the instant invention is prima facie obvious from the teachings of Mayer et al., Earnest et al., ^{and further in view of} King. One of ordinary skill in the art would have known to conjugate

the rhodamine dyes of Mayer et al., at the time the instant invention was made. The motivation ^{the teachings of Earnest et al. and King that Rhodamine dyes} is to make additional fluorescent conjugates. ^{are used as conjugates in biological diagnostic assays.}

Applicants' arguments filed 1/07/02 have been fully considered but they are not persuasive. Applicants contend that "Mayer et al., does not mention conjugation [or] conjugate," and "the other references teach different conjugates." This is not persuasive because applicants cannot show nonobviousness by attacking references individually where the rejection is based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

This is an RCE of applicant's earlier Application No. 09/344,226. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in

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this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Taofiq A. Solola whose telephone number is (703) 308-4690. The examiner is on flexible work schedule and the best days to get him are Mondays, Wednesdays and Fridays.

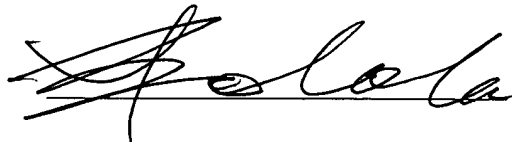
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (703) 308-4537. The fax phone number for this Group is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Taofiq A. Solola', written over a horizontal line.

Taofiq A. Solola, Ph.D.

Primary Examiner

Group 1626

February 2, 2002
